



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814

Phone (916) 445-5014

Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GRAY DAVIS, GOVERNOR

Contact Person: Paul Riches (916) 445-5014

LEGISLATION & REGULATION COMMITTEE

September 11, 2003

Department of Consumer Affairs

400 R Street, Suite 4070

Sacramento, CA 95814

10:30 a.m. – 1:00 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 business days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may be attending and may comment on the committee's agenda.

-
- A. Call to Order** **10:30 a.m.**
- B. Legislation Update.**
- C. Regulation Update.**
- D. Informational Hearing for Regulations Awaiting Notice by the Board of Pharmacy.**
- 1. CCR, Title 16, Section 1709.1 – Pharmacist-In-Charge at Two Locations**
 - 2. CCR, Title 16, Section 1710 – Hospital Central Refill Pharmacies**
 - 3. CCR Title 16, Sections 1717.1 & 1717.2 – Confidentiality of Medical Information**
 - 4. CCR, Title 16, Section 1717.4 – Authenticity of Prescriptions**
 - 5. CCR, Title 16, Section 1793.3 – Elimination of Clerk/Typist Ratio**
- E. Technical Regulation Changes Resulting from 2003 Legislation.**
- F. Public Suggestions for Legislative Changes in 2004.**
- G. Public Suggestions for Future Regulation Changes.**
- H. Review the Committee's Strategic Plan Update.**
- I. Comments from the Public on Items Not on the Agenda**
- J. Setting next meeting date.**

Adjournment

1:00 p.m.

Meeting materials will be posted on the board's website on or before September 2, 2003.

Attachment A

Memorandum

To: Legislation and Regulation Committee

Date: August 25, 2003

From: Paul Riches
Legislative Analyst

Subject: Legislation Update

BOARD SPONSORED LEGISLATION

Senate Bill 361 (Figueroa)

This bill is the board's sunset review legislation. The bill contains the recommendations from the Joint Legislative Sunset Review Committee that require statutory changes including:

- Adoption of NAPLEX
- Add two public members to the board
- Permit non-pharmacists to be board inspectors
- Revision of pharmacy technician qualifications

The bill also contains the board's omnibus items for 2003.

The bill will be heard on the Assembly floor in the coming days. The bill has no opposition at this time and is expected to be signed by the Governor. The bill was recently amended to require periodic evaluation of the NAPLEX and require that one pharmacist board member be a union member. These amendments removed opposition from the United Food and Commercial Workers.

BILLS WITH A BOARD POSITION

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."

Board Position: **Support**

Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medical fraud.

Board Position: **Support**

Status: Senate Floor

AB 1363 (Berg) Establishes requirements for needle exchange programs.

Board Position: **Support**

Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy.

Board Position: **Support**

Status: Two-year bill

SB 151 (Burton) Eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper resistant prescribing pad for all controlled substance prescriptions. Adds Schedule III drugs to CURES.

Board Position: **Support**

Status: Assembly Appropriations Committee

SB 175 (Kuehl) Adds veterinary drugs to the definition of dangerous drugs.

Board Position: **Support**

Status: Enrolled to the Governor

SB 393 (Aanestad) Permits "tech check tech" in hospitals.

Board Position: **Support if Amended**

Status: Two-year bill

SB 490 (Alpert) Establishes a statewide protocol for pharmacists dispensing emergency contraception.

Board Position: **Support**

Status: Assembly Floor

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.

Board Position: **Oppose**

Status: Two-year bill

SB 545 (Speier) Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. Eliminates the training requirement for a pharmacist to dispense emergency contraception.

Board Position: **Neutral**

Status: Assembly Floor

SB 774 (Vasconcellos) Eliminates the prescription requirement for hypodermic needles and syringes.

Board Position: **Support**

Status: Assembly Floor

BILLS OF INTEREST

AB 57 (Bates) Places MDMA into Schedule II.

Status: Assembly Inactive File

AB 186 (Correa) Makes technical changes to the Pharmacy Law relating to optometrists.

Status: Senate Floor

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.

Status: Senate Business and Professions Committee

AB 1196 (Montanez) Permits nurse practitioners to order Schedule II drugs.

Status: Senate Appropriations Committee

SB 292 (Speier) Requires prescription labels to have a description of the drug.

Status: Assembly Floor

Attachment B

Memorandum

To: Legislation & Regulation Committee

Date: August 25, 2003

From: Paul Riches
Legislative Analyst

Subject: Regulations Update

Pending Regulations

Section 1732.05 – Continuing Education

Summary: This regulation will recognize continuing education credits approved by other California health professions licensing boards.

Status: Approved by OAL on July 28, 2003. Effective August 27, 2003.

Section 1751 – Sterile Compounding

Summary: This regulation will establish guidelines for the compounding of sterile drug products.

Status: The board adopted the regulation with changes at the April 29, 2003 board meeting. 15-Day notice is pending.

Section 1775 et seq. – Citation and Fine

Summary: This regulation designates the executive officer as the issuing authority for citations and fines. The regulation also consolidates and recasts existing board regulations relating to citations and fines.

Status: Submitted to OAL on August 19, 2003.

Awaiting Notice

Section 1707.5 – Hospital Central Fill

Summary: This regulation will permit central refill operations for hospitals.

Status: Scheduled for informational hearing at the September 11, 2003 Legislation and Regulation Committee meeting.

Section 1709.1 - Pharmacist-in-Charge at Two Locations

Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.

Status: Scheduled for informational hearing at the September 11, 2003 Legislation and Regulation Committee meeting.

Section 1715 – Pharmacy Self Assessment

Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.

Status: Informational Hearing Required

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records

Summary: This regulation will make any needed changes to board regulations to conform to changes in patient privacy laws.

Status: Scheduled for informational hearing at the September 11, 2003 Legislation and Regulation Committee meeting.

Section 1717.4 – Authentication of Electronic Prescriptions

Summary: This regulation will require pharmacists to authenticate electronic prescriptions.

Status: Scheduled for informational hearing at the September 11, 2003 Legislation and Regulation Committee meeting.

Section 1784 – Wholesaling

Summary: This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances.

Status: Revised draft submitted to the Enforcement Committee.

Section 1793.3 – “Clerk-Typist” Ratio

Summary: This regulation will eliminate the clerk/typist ratio.

Status: Scheduled for informational hearing at the September 11, 2003 Legislation and Regulation Committee meeting.

Attachment C

**Board of Pharmacy
Draft Revisions For Informational Hearing
Pharmacist-In-Charge**

§1709.1. Designation of ~~Pharmacist in Charge~~. Pharmacist-In-Charge.

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. ~~one pharmacy, except that a pharmacist may serve as a pharmacist in charge for two pharmacies if (1) the pharmacist in charge is the only pharmacist at each pharmacy and (2) the pharmacies do not have overlapping hours of business.~~

(c) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the exemptee-in-charge ~~sole pharmacist~~ for a wholesaler, a medical device retailer or a veterinary food-animal drug retailer.

~~A pharmacy may, on an interim basis, designate as the interim pharmacist in charge any registered pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis or in the practice of pharmacy at the pharmacy involved.~~

~~The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of the interim pharmacist in charge with the pharmacy and efforts to obtain and designate a permanent pharmacist in charge.~~

~~The interim basis shall not exceed 120 days.~~

(d) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.

(e) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, 4330, 4331 and 4332, Business and Professions Code.



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**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE & TIME: April 24-26, 2002

LOCATION: Department of Consumer Affairs
Wednesday, April 24, 2002 400 R Street, Hearing Room, Suite 1030
Friday, April 26, 2002 Sacramento, CA 95814

LOCATION: Legislative Office Building
Thursday, April 25, 2002 1020 N Street, Room 100
Sacramento, CA 95814

BOARD MEMBERS

PRESENT: Steven Litsey, President
John Jones, Vice President
Caleb Zia, Treasurer
Robert Elsner
Dave Fong
Stanley Goldenberg
Donald Gubbins
Clarence Hiura
William Powers
John Tilley
Andrea Zinder

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

MOTION: Licensing Committee: Support the board's authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care.

SUPPORT: 9 OPPOSE: 0 ABSTAIN: 1

- **Recommendation to support a scholarship or grant program for pharmacy students to practice in underserved areas.**

Chairperson Gubbins stated that Assemblywoman Virginia Strom-Martin introduced AB 2935 which would provide scholarships and grants to pharmacy students to practice in underserved areas of California. The bill proposes that payment for this scholarship program would be from a special fee paid by pharmacists and pharmacies. These fees would be paid into a fund administered by the Office of Statewide Health Planning and Development. The Task Force supported this proposed solution and the Licensing Committee agreed with the recommendation.

John Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA does not agree that the funding for scholarships and grants should come from all pharmacists and pharmacies as part of the renewal process. He asked that the board support the concept that those who benefit from the program should pay for the program.

MOTION: Licensing Committee: Support a scholarship or grant program for pharmacy students to practice in underserved areas.

SUPPORT: 9 OPPOSE: 1

- **Consideration to authorize a pharmacist to be a pharmacist-in-charge at two pharmacies.**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force voted not to discuss this proposed solution. However, there was agreement that because of the pharmacist shortage and the responsibility required of the pharmacist-in-charge (PIC), it is very difficult for pharmacies to hire a PIC. Because of these dynamics, pharmacists not suitable for the position become the PIC because of the limited options faced by the pharmacy. The board's expectations of the PIC position need to be clearly identified and that pharmacy employers and the board mutually promote a positive image of the position. The pharmacist who becomes

a PIC should want to be a good mentor and role model for staff, promoting the value of good patient care and compliance with pharmacy law.

Chairperson Gubbins stated that the committee discussed that better PICs would result if a PIC could be in charge of two pharmacies. There would be at least one pharmacist in both pharmacies and the PIC would have direct responsibility for both locations, dividing time between the two operations.

Ms. Zinder expressed concern that this would place an additional burden on the PIC to supervise more staff in a situation where he or she may not be able to have adequate control.

Chairperson Gubbins clarified that this would not be mandated, but possible for those PICs who have the professional ability and are capable of taking on the challenge to teach and train others.

Mr. Powers stated that from the consumer's perspective he did not feel that this would be in their best interest and that it could be more difficult to hire qualified PICs to manage two pharmacies.

Mr. Fong stated that under regulation, every pharmacy must have a PIC. He added that the board should articulate the expectations of the PIC and build on a more positive image for PICs.

Mr. Elsner stated that consumers would be better served by a qualified PIC rather than by someone assigned to the position unwillingly.

Shane Gusman, representing the United Food and Commercial Workers, asked if this requires a regulatory change and are there any provisions that address geographical issues.

MOTION: Licensing Committee: Authorize a pharmacist to be a pharmacist-in-charge at two pharmacies.

SUPPORT: 6 OPPOSE: 5

- **Recommendation to modify the exemptee program to clarify the following program requirements: that an applicant be at least 18 years old, has completed a training program of at least 40 hours that provides the applicant with detailed and comprehensive knowledge in specified areas, and the exemptee-in-charge is based in California**

Attachment D

**Board of Pharmacy
Draft Revisions for Informational Hearing
Hospital Central Fill**

§1710. Inpatient Hospital Pharmacy.

(a) For purposes of Business and Professions Code Section 4111, an inpatient hospital pharmacy is a hospital pharmacy pursuant to Business and Professions Code Section 4029 which solely or predominantly furnishes drugs to inpatients of that hospital. A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A licensed inpatient hospital pharmacy may process an order for filling inpatient patient cassettes by another inpatient hospital pharmacy within this state, provided:

- (1) The inpatient hospital pharmacy that is to fill the cassettes either has a contract with the ordering inpatient hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy.
- (2) The filled cassette is delivered directly from one inpatient hospital pharmacy to the ordering inpatient hospital pharmacy.
- (3) Each cassette or container meets the requirements of Business and Professions Code section 4076.
- (4) Both inpatient hospital pharmacies are responsible for ensuring that the order has been properly filled, and
- (5) Both inpatient hospital pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each inpatient hospital pharmacy.
- (6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4111, 4118 and 4380, Business and Professions Code.



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Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

M/S/C: POWERS/ELSNER

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise – at the discretion of the pharmacist

M/S/C: POWERS/TILLEY

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise at the discretion of the pharmacist.

SUPPORT 10 OPPOSE: 0

MOTION: Licensing Committee: Consolidate all staffing ratios in one, and empower the pharmacist to determine appropriate level of staffing pharmacy technicians, clerk typists, typists, interns and technician trainees.

M/S/C: JONES/ZINDER

SUPPORT: 10 OPPOSE: 0

- **Expand the authority for central fill to inpatient hospital pharmacies**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force supported the proposed solution (A-4) to expand the central processing with the following caveats:

- Protect patient confidentiality,
- Assure right to face-to-face counseling
- New prescriptions are transmitted electronically to the pharmacy.
- Ability to check patient profile. Payer usually does crosschecking. (In practice, this might be impossible).
- Electronic data is available to everyone that needs it.
- If done correctly, this process is transparent to patient.
- Any other information that may be pertinent to patient care is available.

Chairperson Gubbins stated that the Licensing Committee clarified that this proposed solution is already authorized under current law. However, the current central fill regulations do not include central fill by hospital inpatient pharmacies.

Chairperson Gubbins noted that if the board approves this recommendation, it will require a regulation change and will be added to the board's strategic objectives for 2002/03.

Mr. Goldenberg stated that in the long-term care practice setting the challenge is delivery of medication in a timely manner without establishing large organizations in multiple arenas.

Ms. Harris stated that current regulation allows for central fill in the community pharmacy only. However, the board has taken the position that it is permissible to use central fill in hospital pharmacies licensed by the Department of Health Services under a consolidated license.

Steve Gray representing Kaiser Permanente stated that Kaiser supports central fill pharmacies because the technology available provides a more accurate filling of cassettes. Mr. Gray added that this technology is expensive but hospitals working together can offset the cost.

MOTION: Licensing Committee: Expand the authority for central fill to inpatient hospital pharmacies.

SUPPORT: 10 OPPOSE: 0

- **Explore the feasibility of offering the California pharmacist licensure examination more than twice a year.**

Chairperson Gubbins stated that the Licensing Committee considered four proposals for the Pharmacy Manpower Task Force that were related to increasing the administration of the California pharmacist licensure examination or providing options to applicants who failed only one section of the examination. They were:

- Offer the exam more than two times per year with the goal of moving toward offering the exam on a continuous basis.
- Consider re-testing the multiple choice or essay section only if only one portion is failed and evaluate whether the essay adequately measures what it is supposed to do.
- The task force rejects the idea of a temporary one-year license for out of state pharmacists; however it was suggested that a temporary license should be considered for an applicant who is a licensed out-of-state pharmacist and who has passed at least one section of the examinations.
- The task force rejects the notion of increasing the number of failed attempts from four to six before an applicant has to take additional coursework.

Mr. Riches referred to AB 2165 (Strom-Martin) that was heard in the Assembly Health Committee on April 18. The bill was passed by the committee and is scheduled for hearing in the Assembly Appropriations Committee next. Mr. Riches noted that in its

Attachment E

Board of Pharmacy
Draft Revisions For Informational Hearing
Confidentiality of Medical Information

§1717.1. Common Electronic Files.

- (a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.
- (b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.
- (c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.
- (d) Prescription information may not be included in a common electronic file unless a valid authorization to release medical information pursuant to Section 56.11 of the Civil Code is provided.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

1717.2. Notice of Electronic Prescription Files.

- ~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist in charge.~~

- ~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~(date)~~

~~(signature of patient)~~

~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient.
The original shall be maintained by the pharmacy for three years from the date of the last filling
or refilling of any prescription in the name of the consumer.~~

Authority cited: Sections 4008 and 4008.2, Business and Professions Code.

Reference: Sections 4008 and 4008.2, Business and Professions Code.

Attachment F

**Board of Pharmacy
Draft Revisions For Informational Hearing
Authenticity of Prescriptions**

§1717.4. Electronic Transmission of Prescriptions.

- (a) Except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy.
- (b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.
- (c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.
- (d) An "interim storage device" means an electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.
- (e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.
- (f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.
- (g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.
- (h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.



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GRAY DAVIS, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: April 12 and 13, 2000

TIME: 8:00 a.m. - 5:00 p.m.

LOCATION: Department of Consumer Affairs
400 R Street, Hearing Room #1030
Sacramento, CA 95814

BOARD MEMBERS

PRESENT:

Richard Mazzoni, President
Robert Elsner, Vice President
Darlene Fujimoto – April 13, 2000 only
Andrea Zinder
John Jones
Steven Litsey
Donald Gubbins
M. Standifer Shreve

BOARD MEMBERS

ABSENT:

Holly Strom
Caleb Zia
Sandra Bauer

STAFF

PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Gilbert Castillo, Supervising Inspector
William Marcus, Deputy Attorney General
LaVonne Powell, Department Legal Counsel

LICENSING COMMITTEE REPORT

Ms. Harris reported that there has been no Licensing Committee Meeting since the January board meeting, but a licensing staff meeting was held March 28, 2000.

Ms. Harris stated that the Licensing Committee held two informational hearings on the issue of pharmacy manpower in September of 1999 and January of 2000 - the pharmacist shortage, reciprocity, use of ancillary pharmacy personnel, and automation. The Licensing Committee will examine what if any action the board should take regarding reciprocity (the use of the NABPLEX), but this must wait until the board has completed its review of the NABPLEX examination. The board is in the process of completing the job analysis for the California examination. Once this is completed, the board will contract with the Department of Consumer Affairs, Office of Examination Resources to conduct the review of the national exam. This will begin by January 2001. However, this timeline is contingent upon the status of the job analysis for NABPLEX, which must be completed before the board's review.

The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA) is conducting a study required under the Healthcare Research and Quality Act of 1999, to determine how many pharmacists will be needed to fill America's prescription needs. HRSA is inviting all interested parties to submit resource information, data and documented studies that verify pharmacist shortages. Comments are due by May 1, 2000.

Licensing staff recommended that the board submit comments regarding California laws governing the use of technicians to fill prescriptions, the use of technology to assist pharmacists, and the current pharmacist education process including any policy positions that the board may take in these areas. The board also may want to point out outdated and restrictive federal pharmacy requirements that restrict the ability of pharmacists to provide pharmacists care.

Electronic Transmission of Prescriptions

Ms. Harris reported that the board has received many requests to approve use of various electronic systems that allow for the transmission of prescriptions from the prescriber to the pharmacy. There are many variants that are available and the Internet offers on-line services that receive an order from a prescriber and forward it to a pharmacy for dispensing. The board's focus is on its licensees who use any electronic systems to receive or maintain prescription and patient information, and any out-of-state pharmacies who use such systems to dispense medications to California residents.

Regulation 1717.4(h) requires that any person who transmits, maintains, or receives any prescription refill electronically must also ensure the security, integrity, and confidentiality of the order and any information contained in it. The pharmacy should also take necessary steps to ensure the authenticity of the order and the authority of the

person issuing it as well as the person or entity from which it is received by the pharmacy.

Board staff recommended that the board amend 1717.4, as follows:

Any person who transmits, maintains, or receives any prescription refill electronically must ensure the security, integrity, ~~and confidentiality~~, and authenticity of the order and any information contained in it.

John Cronin stated that in most cases where transactions are occurring, there is some type of contractual relationships between the prescriber and the company that operates the technology. The company is actually the agent of the doctor or the prescriber. Ultimately, the transmission is from the company directly to the pharmacy. The relationship is only through the company and the prescriber.

Ms. Herold commented that ultimately it is the prescriber that activates the process used to electronically transmit a prescription; the pharmacy is only the receiver. Consequently, the pharmacy must ensure that that the prescription is authentic, but the prescriber must assure the process selected is confidential.

Steve Gray stated that he supports the proposed language modification to Section 1717.4.

MOTION: Amend California Code of Regulations section 1717.4, as follows:

Any person who transmits, maintains, or receives any prescription refill electronically must ensure the security, integrity, ~~and confidentiality~~, and authenticity of the order and any information contained in it.

M/S/C: ELSNER/SHREVE

SUPPORT: 7 OPPOSE: 0

Cooky Quandt commented that in dealing with electronically transmitted prescriptions, pharmacists greatly appreciate receiving prescriptions that they can read. She added that this is a very important issue and the board should continue to look at new ways to transmit prescriptions.

Ms. Harris reported that the April Newsletter will include information on this topic.

Mr. Marcus stated that the problem with electronic transfers of prescriptions is the federal regulations that clearly define a fax as a copy of an original signed prescription. He noted that the federal government is exploring the approval of electronic data transmission for all controlled substances.

Attachment G

**Board of Pharmacy
Draft Revisions for Informational Hearing
Clerk-Typist Ratio**

§1793.3. Other Non-Licensed Pharmacy Personnel.

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization. ~~There shall be no more than one non-licensed person, other than a pharmacy technician, performing the tasks specified in this section for each registered pharmacist on duty.~~

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall notify the pharmacist-in-charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the non-licensed personnel that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule.

(d) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Sections 4005 and 4007, Business and Professions Code. Reference: Sections 4005 and 4007, Business and Professions Code.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE & TIME: April 24-26, 2002

LOCATION: Department of Consumer Affairs
Wednesday, April 24, 2002 400 R Street, Hearing Room, Suite 1030
Friday, April 26, 2002 Sacramento, CA 95814

LOCATION: Legislative Office Building
Thursday, April 25, 2002 1020 N Street, Room 100
Sacramento, CA 95814

BOARD MEMBERS

PRESENT: Steven Litsey, President
John Jones, Vice President
Caleb Zia, Treasurer
Robert Elsner
Dave Fong
Stanley Goldenberg
Donald Gubbins
Clarence Hiura
William Powers
John Tilley
Andrea Zinder

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

M/S/C: ZINDER/ELSNER

SUPPORT: 10 OPPOSE: 0

MOTION: Licensing Committee: The Board of Pharmacy supports the increase in the number of interns that a pharmacist can supervise from one to two, at the discretion of the pharmacist.

SUPPORT 10 OPPOSE: 0

- **Support the increase in the number of clerk-typists that a pharmacist can supervise**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force did not support this proposed solution because it eliminates the clerk-typist ratio and places no controls on the number of clerk-typists in addition to the other ancillary personnel that a pharmacist may be required to supervise.

Chairperson Gubbins stated that the committee discussed the reason for this proposed solution and one of the most significant impacts to the community pharmacist is the clerical processing of insurance claims. And while the clerk-typist classification is not required for insurance processing, it is done real-time when the clerk-typist enters the prescription information into the computer. When a problem arises with an insurance claim, the clerk-typist must stop what he or she is doing and resolve it. Because of the limitation of one-clerk-typist to one pharmacist, the pharmacist is unable to add clerk-typists to process prescriptions. Then the pharmacist is pulled away to either resolve the insurance issue or perform the clerical function of processing the prescription.

Chairperson Gubbins stated that the Licensing Committee modified the proposed solution; however, it did not recommend a specific ratio. If the board adopts this recommendation, it would be added as a strategic objective for the Licensing Committee to determine how many clerk-typists a pharmacist would be authorized to supervise. This proposal would require a regulation change.

Ms. Zinder stated that she opposes this recommendation because it is open-ended and would result in more supervision responsibility for the pharmacist and less patient care.

Mr. Tilley stated that he supports this recommendation because often in small practice settings the pharmacist becomes the problem solver for the insurance companies.

Mr. Jones stated that he would favor a more flexible standard where the pharmacist could make the determination of staffing needs based on the type of the practice setting.

MOTION: Amend the language to include “at the discretion of the pharmacist”

M/S/C: POWERS/ELSNER

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise – at the discretion of the pharmacist

M/S/C: POWERS/TILLEY

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise at the discretion of the pharmacist.

SUPPORT 10 OPPOSE: 0

MOTION: Licensing Committee: Consolidate all staffing ratios in one, and empower the pharmacist to determine appropriate level of staffing pharmacy technicians, clerk typists, typists, interns and technician trainees.

M/S/C: JONES/ZINDER

SUPPORT: 10 OPPOSE: 0

- **Expand the authority for central fill to inpatient hospital pharmacies**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force supported the proposed solution (A-4) to expand the central processing with the following caveats:

- Protect patient confidentiality,
- Assure right to face-to-face counseling
- New prescriptions are transmitted electronically to the pharmacy.
- Ability to check patient profile. Payer usually does crosschecking. (In practice, this might be impossible).
- Electronic data is available to everyone that needs it.
- If done correctly, this process is transparent to patient.
- Any other information that may be pertinent to patient care is available.

Chairperson Gubbins stated that the Licensing Committee clarified that this proposed solution is already authorized under current law. However, the current central fill regulations do not include central fill by hospital inpatient pharmacies.